IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and KAI PHARMACEUTICALS, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA INC., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Amgen Inc. ("Amgen") and KAI Pharmaceuticals, Inc. ("KAI") (collectively "Plaintiffs") by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively "Aurobindo") of Abbreviated New Drug Application ("ANDA") No. 215840 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL ("Aurobindo's Proposed ANDA Product") prior to the expiration of U.S. Patent Nos. 9,820,938 ("the '938 patent") and 10,344,765 ("the '765 patent") (collectively "the Asserted Patents"). Aurobindo notified Plaintiffs that it had submitted this ANDA by a letter received March 26, 2021 ("Notice Letter"). Upon information and belief, Aurobindo's Proposed ANDA Product will be marketed as a competing product to Parsabiv® (etelcalcetide), a product developed by Plaintiffs for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

PARTIES

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

3. Plaintiff KAI is a corporation organized and existing under the laws of Delaware, having a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320. KAI is a wholly owned subsidiary of Amgen.

4. Upon information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India, having a place of business at Plot No. 11, Water Mark Building, Hitech City Road, Whitefields, Kondapur, Hyderabad, Telangana 500084, India. Upon information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA Inc., throughout the United States, including in Delaware.

5. Upon information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Upon information and belief, Aurobindo Pharma USA Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited. Upon information and belief, Aurobindo Pharma USA Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

6. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or

distribution of pharmaceutical products. Upon further information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. are agents of each other and/or operate in concert as integrated parts of the same business group.

7. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. acted in concert to develop Aurobindo's Proposed ANDA Product that is the subject of ANDA No. 215840 and to seek regulatory approval from the FDA to market and sell Aurobindo's Proposed ANDA Product throughout the United States, including in Delaware.

8. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. intend to act collaboratively to obtain approval for Aurobindo's ANDA No. 215840, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Aurobindo Pharma USA Inc. because, on information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma USA Inc. has consented to general jurisdiction in Delaware.

11. This Court has personal jurisdiction over Aurobindo Pharma Limited because, *inter alia*, Aurobindo Pharma Limited, itself and through its subsidiary Aurobindo Pharma USA Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should

reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma Limited, itself and through its subsidiary Aurobindo Pharma USA Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because, among other things, on information and belief: (1) Aurobindo Pharma Limited and its subsidiary Aurobindo Pharma USA Inc. filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma Limited and its subsidiary Aurobindo Pharma USA Inc. will market, distribute, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's Proposed ANDA Product in Delaware. On information and belief, upon approval of Aurobindo's ANDA, Aurobindo's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

13. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Amgen and KAI, both Delaware corporations.

14. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it regularly engages in patent litigation concerning Aurobindo's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 20-01528 (D. Del.); *Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-00853 (D. Del.).

15. In addition, to the extent personal jurisdiction does not exist over Aurobindo Pharma Limited in Delaware, this Court has personal jurisdiction over it under Federal Rule of Civil Procedure 4(k)(2) because Aurobindo Pharma Limited is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over it is consistent with the United States Constitution and laws.

16. For at least the above reasons, it would not be unfair or unreasonable for Aurobindo Pharma Limited to litigate this action in this District, and Aurobindo Pharma Limited is subject to personal jurisdiction in this District.

17. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Aurobindo Pharma USA Inc., at least because, on information and belief, Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

18. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to Aurobindo Pharma Limited, at least because, on information and belief, Aurobindo Pharma Limited is a foreign corporation that may be sued in any judicial district.

BACKGROUND

PARSABIV® (ETELCALCETIDE)

19. On February 7, 2017, the FDA granted approval to market Parsabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

20. The active pharmaceutical ingredient in Parsabiv® is etelcalcetide, which was invented by scientists at KAI and developed by KAI and Amgen. Etelcalcetide is a synthetic peptide calcium-sensing receptor agonist. It is a calcimimetic agent that allosterically modulates the calcium-sensing receptor ("CaSR"). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases parathyroid hormone ("PTH") secretion.

21. Parsabiv® (etelcalcetide) is FDA approved for intravenous injection. It is FDA approved as a sterile, preservative-free, ready-to-use clear and colorless solution in a single-dose vial containing 5 mg/mL of etelcalcetide. Each vial contains 2.5, 5, or 10 mg etelcalcetide. Each vial is formulated with 0.85% weight/volume sodium chloride, 10 mM succinic acid, and adjusted to pH 3.3 with sodium hydroxide and/or hydrochloric acid.

22. Amgen, itself or through a subsidiary, markets Parsabiv® (etelcalcetide) in the United States pursuant to approved New Drug Application ("NDA") No. 208325.

23. KAI, a wholly owned subsidiary of Amgen, is the holder of approved NDA No. 208325 for Parsabiv® (etelcalcetide).

24. The '938 and '765 patents are listed for NDA No. 208325 for Parsabiv® (etelcalcetide) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

25. The ’938 patent, titled “Stable Liquid Formulation of AMG 416 (Etelcalcetide),” was duly and legally issued on November 21, 2017. A copy of the ’938 patent is attached as Exhibit A.

26. Plaintiffs own and have rights to the ’938 patent.

27. There is an actual case or controversy between the parties regarding Aurobindo’s liability for its infringement of the ’938 patent.

28. The ’765 patent, titled “Stable Liquid Formulation of AMG 416 (Etelcalcetide),” was duly and legally issued on July 9, 2019. A copy of the ’765 patent is attached as Exhibit B.

29. Plaintiffs own and have rights to the ’765 patent.

30. There is an actual case or controversy between the parties regarding Aurobindo’s liability for its infringement of the ’765 patent.

AUROBINDO’S ANDA

31. On March 26, 2021, Plaintiffs received Aurobindo’s Notice Letter, which informed Plaintiffs that Aurobindo seeks through ANDA No. 215840 approval to engage in the commercial manufacture, use, sale, or offer for sale of Aurobindo’s Proposed ANDA Product prior to the expiration of the Asserted Patents. According to the Notice Letter, included within ANDA No. 215840 is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Aurobindo’s Proposed ANDA Product.

32. On information and belief, Aurobindo included within ANDA No. 215840 a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III Certification”) that Aurobindo is not seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo’s Proposed ANDA Product prior to the expiration of

U.S. Patent Nos. 8,377,880, 8,999,932, 9,278,995, and 9,701,712, which are also listed in the Orange Book for NDA No. 208325 for Parsabiv® (etelcalcetide).

33. This action is being filed within 45 days of Plaintiffs' receipt of Aurobindo's Notice Letter.

34. Aurobindo was aware of the Asserted Patents when ANDA No. 215840 was filed with a Paragraph IV Certification.

35. On information and belief, etelcalcetide is the active ingredient in Aurobindo's Proposed ANDA Product. On information and belief, Aurobindo's Proposed ANDA Product is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0.

36. On information and belief, ANDA No. 215840 refers to and relies upon the NDA for Parsabiv® (etelcalcetide) and contains data that, according to Aurobindo, demonstrate bioequivalence of Aurobindo's Proposed ANDA Product and Parsabiv® (etelcalcetide), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or Aurobindo has sought a waiver of the requirement to demonstrate bioequivalence of its Proposed ANDA Product and Parsabiv® (etelcalcetide).

37. On information and belief, Aurobindo intends to have healthcare providers use its Proposed ANDA Product, if approved, as set forth in its Proposed ANDA Product label. On information and belief, Aurobindo's Proposed ANDA Product label will instruct healthcare providers to prescribe Aurobindo's Proposed ANDA Product in the manner set forth in the label.

COUNT I
(Infringement of the '938 Patent)

38. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

39. Claim 1 of the ’938 patent covers “[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0.”

40. Upon information and belief, Aurobindo’s Proposed ANDA Product is covered by one or more claims of the ’938 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0.

41. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo’s Proposed ANDA Product, or the use of Aurobindo’s Proposed ANDA Product in accordance with and as directed by Aurobindo’s proposed labeling for that product, will infringe one or more claims of the ’938 patent, including at least claim 1, either literally or under the doctrine of equivalents.

42. Upon information and belief, Aurobindo filed as part of ANDA No. 215840 a Paragraph IV Certification, asserting that the claims of the ’938 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Aurobindo’s Proposed ANDA Product.

43. Aurobindo did not contend in its Notice Letter that Aurobindo’s Proposed ANDA Product, or the use of Aurobindo’s Proposed ANDA Product in accordance with and as directed by Aurobindo’s proposed labeling for that product, would not infringe claims 1-14 of the ’938 patent.

44. Aurobindo has no reasonable basis to believe that Aurobindo’s Proposed ANDA Product, or the use of Aurobindo’s Proposed ANDA Product in accordance with and as directed by Aurobindo’s proposed labeling for that product, would not infringe one or more valid claims of the ’938 patent.

45. The purpose of filing ANDA No. 215840 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '938 patent.

46. Aurobindo's submission of ANDA No. 215840 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '938 patent is an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, sale and/or offer for sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215840 and any amendments thereto, *i.e.*, prior to the expiration of the '938 patent.

48. Upon information and belief, Aurobindo has knowledge of the '938 patent at least because the '938 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, Aurobindo continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215840 and any amendments thereto.

49. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '938 patent when ANDA No. 215840 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '938 patent. Further upon information and belief, Aurobindo plans and intends to, and will, do so immediately and imminently upon approval.

50. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '938 patent and active inducement of infringement of the '938 patent, either literally or under the doctrine of equivalents.

51. Unless Aurobindo is enjoined from infringing the '938 patent and actively inducing infringement of the '938 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '765 Patent)

52. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

53. Claim 1 of the '765 patent covers "[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] hydrochloride in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0."

54. Upon information and belief, Aurobindo's Proposed ANDA Product is covered by one or more claims of the '765 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide hydrochloride in an aqueous solution having a pH of 2.0 to 5.0.

55. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product, will infringe one or more claims of the '765 patent, including at least claim 1, either literally or under the doctrine of equivalents.

56. Upon information and belief, Aurobindo filed as part of ANDA No. 215840 a Paragraph IV Certification, asserting that the claims of the '765 patent are invalid, unenforceable,

and/or not infringed by the manufacture, use, offer for sale, or sale of Aurobindo's Proposed ANDA Product.

57. Aurobindo did not contend in its Notice Letter that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product, would not infringe claims 1-14 of the '765 patent.

58. Aurobindo has no reasonable basis to believe that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product, would not infringe one or more valid claims of the '765 patent.

59. The purpose of filing ANDA No. 215840 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '765 patent.

60. Aurobindo's submission of ANDA No. 215840 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '765 patent is an act of infringement of the '765 patent under 35 U.S.C. § 271(e)(2)(A).

61. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, sale and/or offer for sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215840 and any amendments thereto, *i.e.*, prior to the expiration of the '765 patent.

62. Upon information and belief, Aurobindo has knowledge of the '765 patent at least because the '765 patent is listed in the FDA's *Orange Book: Approved Drug Products with*

Therapeutic Equivalence Evaluations for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, Aurobindo continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215840 and any amendments thereto.

63. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '765 patent when ANDA No. 215840 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '765 patent. Further upon information and belief, Aurobindo plans and intends to, and will, do so immediately and imminently upon approval.

64. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '765 patent and active inducement of infringement of the '765 patent, either literally or under the doctrine of equivalents.

65. Unless Aurobindo is enjoined from infringing the '765 patent and actively inducing infringement of the '765 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Aurobindo's submission of ANDA No. 215840 to the FDA was an act of infringement of one or more claims of the Asserted Patents;

(b) A judgment that Aurobindo's making, using, offering to sell, selling, marketing, distributing, or importing into the United States Aurobindo's Proposed ANDA Product prior to the

expiration of the Asserted Patents will infringe and/or will actively induce infringement of one or more claims of the Asserted Patents;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Aurobindo, Aurobindo's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Aurobindo, from making, using, selling, offering to sell, marketing, distributing, or importing Aurobindo's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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